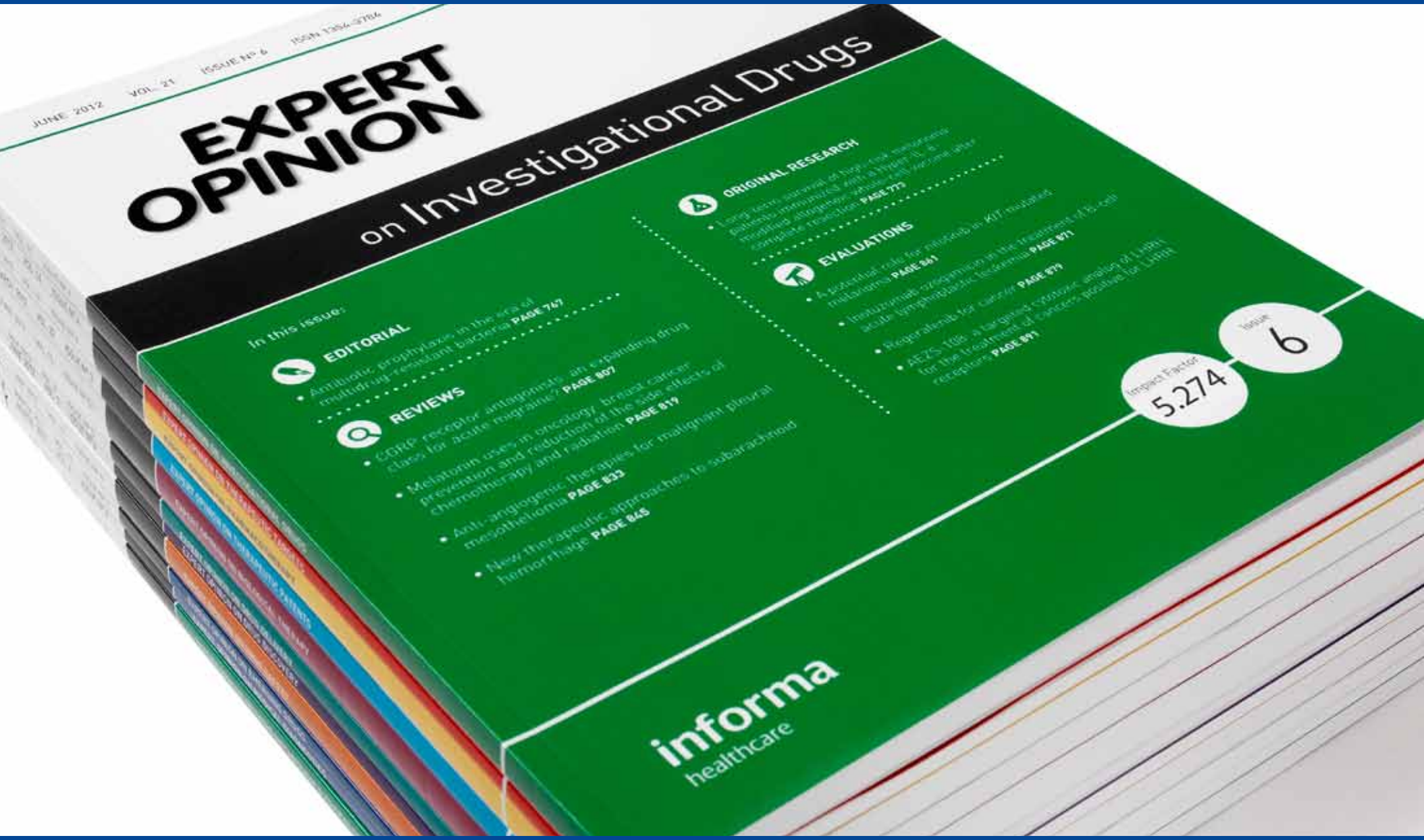

EXPERT OPINION

PRE-CLINICAL
PHASE I
PHASE II
PHASE III
PHASE IV

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Expert Opinion is a review series of 11 journals providing overviews and analysis at every stage of the R&D pipeline

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- 11 peer reviewed journals; 10 indexed by MEDLINE
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- Ranked in the top quartile of the Thomson Reuters Pharmacology and Pharmacy category
- *Expert Opinion on Therapeutic Patents* ranked 1st in the Thomson Reuters Medicine, Legal category
- Published by Informa Healthcare
- Member of the Committee on Publication Ethics (COPE)

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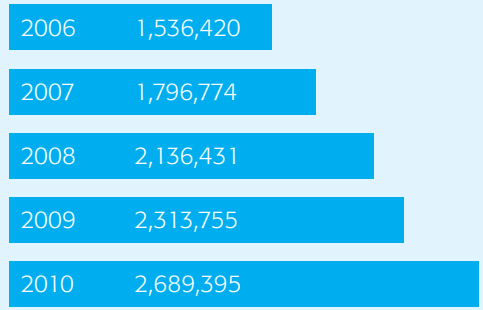

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Reviews

The *Expert Opinion* series publishes reviews on all therapy areas that ends not with the "Conclusion", but with an "Expert Opinion". This is where our authors, all internationally recognised experts in their field and key opinion leaders within the industry, give their own personal view. They put their knowledge, expertise and experience to the test, stating where the research is now, where it should go next, and how it should get there.

Expert Opinion on Therapeutic Patents publishes reviews covering recent patent claims on compounds or applications with therapeutic potential.

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Expert Opinion on Investigational Drugs publishes reviews covering preclinical through to Phase II data on drugs or drug classes for specific indications, and their potential impact on future treatment strategies.

Expert Opinion on Biological Therapy publishes reviews covering gene therapy and gene transfer technologies; therapeutic peptides and proteins; vaccines and antibodies; cell-based therapies, stem cell therapies and regenerative medicine; and tissue-based therapies.

Expert Opinion on Drug Delivery publishes reviews covering delivery technologies, vehicles and devices; nanotechnology; novel formulations; the delivery of specific drugs and therapeutic classes; gene/vaccine delivery strategies and modes of entry into the body.

Expert Opinion on Drug Metabolism and Toxicology publishes reviews covering metabolic, pharmacokinetic and toxicological issues relating to specific drugs, drug-drug interactions, drug classes or their use in specific populations; issues relating to enzymes involved in the metabolism, disposition and excretion of drugs; techniques involved in the study of drug metabolism and toxicology; and novel technologies for obtaining ADME-Tox data.

Expert Opinion on Emerging Drugs publishes structured reviews on Phase II and Phase III drugs/drug classes emerging onto the market across all therapy areas, looking at their potential impact on the current management of specific diseases. Articles take the form of analytical reports and provide a view of the competitive landscape.

Expert Opinion on Pharmacotherapy publishes reviews of newly approved and near-to-launch drugs. Articles provide an overview of disease states and current therapeutic management, with a focus on pharmacological treatment.

Expert Opinion on Drug Safety publishes reviews covering occurrence, management and prevention of drug-associated adverse events; risk-benefit analyses of individual drugs and drug classes; safety in 'at-risk' patient populations; comparative tolerability studies; pharmacovigilance and pharmacoepidemiological studies.


Drug Evaluation

Expert Opinion

1. Introduction
2. Overview of the market
3. Introduction to the drug
4. Pharmacodynamics
5. Pharmacokinetics and metabolism
6. Clinical efficacy
7. Other clinical trials
8. Safety and tolerability
9. Regulatory affairs
10. Conclusions
11. Expert opinion

Olopatadine nasal spray for the treatment of seasonal allergic rhinitis in patients aged 6 years and older

Peter S Roland[1], Matthew W Ryan & G Michael Wall

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Importance of the field: Allergic rhinitis is an IgE-mediated condition that produces inflammation of the mucosa of the nose, paranasal sinuses and, frequently, of the ocular conjunctiva. Allergic rhinitis causes a significant disease burden in terms of quality of life, lost productivity and medical treatment costs. One of the newest treatments approved by the FDA is Patanase® (olopatadine hydrochloride) Nasal Spray, 665 µg/spray (OLO). Olopatadine is an antihistamine with selective H_1-receptor antagonist activity.

Areas covered in this review: This review details the basic and clinical research on the olopatadine molecule and OLO nasal spray from 1996 to the present day.

What the reader will gain: The reader will gain a better understanding of the pharmacology of OLO nasal spray, the clinical trial data that have established the efficacy of OLO nasal spray and the overall role of OLO nasal spray in the management of allergic rhinitis.

Take home message: Olopatadine nasal spray is one of the newest treatments approved by the FDA for the management of allergic rhinitis. OLO has a rapid onset of action, efficacy comparable to intranasal steroid sprays and is approved for seasonal allergic rhinitis in patients aged ≥ 6 years.

Keywords: allergic rhinitis, allergic rhinosinusitis, antihistamine, mast cell stabilizer, nasal spray, olopatadine hydrochloride, Patanase® Nasal Spray

Expert Opin. Pharmacother. (2010) 11(9):1559-1567

1. Introduction

Allergic rhinitis is an IgE-mediated allergic response that produces inflammation of the mucosa of the nose, paranasal sinuses and, frequently, of the ocular conjunctiva. Nasal symptoms include nasal obstruction, rhinorrhea, itching and sneezing [1]. Ocular symptoms consist of itching, erythema and 'watery eyes'. In addition to the primary nasal and ocular symptoms, individuals with allergic rhinitis frequently complain of generalized somatic symptoms which interfere with quality of life, for example fatigue, sleep disturbance, irritability, decreased alertness, performance deficits, mood and cognitive impairment [2,3]. Other significant medical conditions are often associated with allergic rhinitis including asthma, Eustachian tube dysfunction, otitis media, rhinosinusitis, nasal polyposis and allergic dermatitis [4]. Allergic rhinitis is usually divided into seasonal allergic rhinitis (SAR), which occurs in response to plant pollens (typically spring and fall), and perennial allergic rhinitis (PAR; typically year-round), which occurs in response to house dust, mites, molds and animal danders [5]. Affecting more than 40 million Americans, allergic rhinitis is considered the fifth most chronic common illness among adults and the most

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1559

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Reader
University of Maryland

Evaluation articles

Drug Evaluations, Treatment Evaluations, Clinical Trial Evaluations, Key Paper Evaluations, Technology Evaluations, Patent Evaluations

DRUG EVALUATIONS

Drug Evaluations are a key feature of the *Expert Opinion* series. *Expert Opinion* Drug Evaluations are 3,000-word articles presenting an overview of the clinical experience with, and efficacy of, a specific compound incorporating basic information on disease incidence and prevalence, unmet medical need, and present treatment guidelines (highlighting regional variations where appropriate).

TREATMENT EVALUATIONS

Treatment Evaluations review the clinical data on a drug for its approved indication. The purpose of the Treatment Evaluation is to promote best practice in the use of the drug and in providing a meaningful comparison of drugs approved for the indication help guide physicians in treatment choices.

CLINICAL TRIAL EVALUATIONS

Clinical Trial Evaluations review the quality of design and implementation of a pivotal study. An independent KOL states what the impact of this study will be on the future of this drug or the therapy area as a whole.

TECHNOLOGY EVALUATIONS

Technology Evaluations review the theory and principles behind a particular technology, its mechanisms of action, potential applications and comparison with competing technologies.

PATENT EVALUATIONS

Patent Evaluations review the scientific and/or commercial rationale behind a particular patent. Authors give their opinion as to whether the compounds described are likely to become lead candidates for development, or if any of the techniques disclosed will be of potential therapeutic use.

KEY PAPER EVALUATIONS

Key Paper Evaluations review the scientific rationale behind a topical paper and give some perspective on the information disclosed, placing it in context with previous research and indicate the importance of this new work.

Evaluation articles:

Development of semagacestat (LY450139), a functional Y-secretase inhibitor, for the treatment of Alzheimer's disease
David B Henley, Patrick C May, Robert A Dean, Eric R Siemers
Expert Opinion on Pharmacotherapy
Vol. 10, No. 10, July 2009
Abstract views: 911

Insights from the dabigatran versus warfarin in patients with atrial fibrillation (RE-LY) trial
Chee W Khoo, Gregory YH Lip
Expert Opinion on Pharmacotherapy
Vol. 11, No. 4, March 2010
Abstract views: 906

Linagliptin, a xanthine-based dipeptidyl peptidase-4 inhibitor with an unusual profile for the treatment of type 2 diabetes
Carolyn F Deacon, Jens J Holst
Expert Opinion on Investigational Drugs
Vol. 19, No. 1, January 2010
Abstract views: 797

Aflibercept (AVE0005): an alternative strategy for inhibiting tumour angiogenesis by vascular endothelial growth factors
Quincy Siu-Chung Chu
Expert Opinion on Biological Therapy
Vol. 9, No. 2, February 2009
Abstract views: 349

All statistics as of 9th November 2011.

The *Expert Opinion* series

	DRUG DISCOVERY		PRECLINICAL		PHASE I
					
Coverage	Technological advances and developments in pharmaceutical patents, with a strong medicinal chemistry focus	Novel techniques for the identification and validation of potential lead compounds and targets	Medical diagnostics, including coverage of genomic- and proteomic-based approaches, and diagnostic patents and devices	Novel molecular drug targets and their potential for drug discovery/ disease treatment	Drugs and drug classes in early clinical development
Phase	Discovery	Discovery - Pre-clinical	Discovery, with post-launch reviews	Discovery - Pre-clinical	Phase I to Phase II
MEDLINE-indexed?	Yes	In review	No	Yes	Yes
Impact Factor*	3.571	2.116	No	3.716	5.274
What our readers say	"...fulfils the role of putting the information contained in patents into a context scientists can understand." - Reader, formerly GlaxoSmithKline	"...is an important new journal providing high quality reviews of key technological, strategic and therapeutic developments in the complex and rapidly evolving drug discovery arena." - Reader, Cancer Research UK	"...enables rapid introduction of novel developments into a clinical environment by allowing comprehensive reviews and updates in an excellent format to become available to the larger community." - Author, University of Edinburgh	"...is unique - no-one else does what it does." - Reader, Argenta	With a strong emphasis on high academic standards, EOID is an ideal platform to enable your work to reach the widest available audience, and get the recognition it deserves in a highly demanding field." – Author, University of Athens

2011 Journal Citation Reports® (Thomson Reuters, 2011)

	PHASE II		PHASE III		LAUNCH
					
Discovery, development and clinical application of vaccines, antibodies, stem cells, genetic therapies and hormone- or protein-based therapies	Drug delivery technologies and new drug formulations	Approaches in the ADME-Tox arena, as well as metabolic, pharmacokinetic and toxicological issues relating to specific drugs or drug classes	Focus on drugs coming up through the pipeline, analysis on what the next drugs to come on to the market are likely to be and their impact on disease management	Newly approved/near to launch drugs and drug classes	Post-marketing/pharmacovigilance studies and safety/adverse event profiles of marketed drugs
Discovery to post-launch	Discovery to Phase II, with post-launch reviews	Phase II and post-launch	Phase II - Phase III	Phase III - Post-launch	Phase IV - Post-launch
Yes	Yes	Yes	Yes	Yes	Yes
3.505	4.896	3.119	3.207	3.205	3.015
"...has provided expert commentary that distills, explains, and prioritizes the issues, frequently identifying technologies that may seem to be outside the box." - Reader, Duke University Medical Center	"It is one of very few places where you can find high quality in-depth reviews of inhalation technology and other issues connected with inhaled drug delivery." - Editorial Advisory Board member	"...has published excellent reviews in the field establishing itself as an important reference for those in academia and industry." - Reader, Gilead	"...provides insightful articles that are very useful for clinicians. They are well written, comprehensive and are an excellent resource for assessing future therapies." - Reader, Cedars-Sinai	"I am impressed by the quality of the journal. The papers published are scientifically excellent, up-to-date and they timely address the most relevant topics of current pharmacological research." - Reader, University of Pisa	"Each issue contains high quality topical reviews, commentary on safety and regulatory issues and is the best place to find the opinions of experts in the field." - Reader, Southampton General Hospital

Our ethics

QUICK FACTS

- All *Expert Opinion* titles are members of the Committee on Publication Ethics (COPE)
- All *Expert Opinion* titles are independently peer-reviewed and require full author disclosures
- *Expert Opinion* adheres to the principles of Uniform Requirements for Manuscripts Submitted to Biomedical Journals, prepared by the ICMJE and the NLM guidelines for published articles and supplements
- *Expert Opinion* is published by Informa Healthcare, the publisher of the original Good Publication Practice (GPP) guidelines

Our content influences patient care decisions. With this comes enormous responsibility to safeguard the medical community from fraudulent or misguiding data. We not only follow industry standards of publication ethics, we have taken a leading role in pushing them further.

In 2003, our sister journal *Current Medical Research & Opinion (CMRO)* published the first Good Publication Practice guidelines. The aim of the guidelines was to ensure that clinical trials sponsored by pharmaceutical companies were published in a responsible and ethical manner. The guidelines quickly established a common standard for all industry-sponsored research and continue to do so today.

We continue to take an active role in organizations that endorse publication ethics. In January 2010, we joined COPE – more details follow. Supported by our vast network of industry experts, we remain vigilant against publication abuses in every title that we publish.

COMMITTEE ON PUBLICATION ETHICS (COPE)

The Committee on Publication Ethics (COPE) is a charity registered in the UK. With over 7,000 members, it is concerned with the integrity of peer-reviewed publications in science, particularly biomedicine. COPE provides a forum for publishers and editors of scientific journals to discuss issues relating to the integrity of the work submitted to or published in their journals.

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Created by the International Committee of Medical Journal Editors (ICMJE), the Uniform Requirements address the ethical principles related to the process of evaluating, improving, and publishing manuscripts in biomedical journals, and the relationships among editors and authors, peer reviewers, and the media. A copy of the most recent Uniform Requirements can be found at www.icjme.org.

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